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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,626	01/08/2002	Alison L. Sparks	4085-251-27	9254

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Supervisor, Patent Prosecution Services
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EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,626	SPARKS, ALISON L.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 November 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-52 is/are pending in the application.
 4a) Of the above claim(s) 1-7 and 16-52 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 8-15 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/3/02; 9/25/02; 11/16/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

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1) In the Abstract, line 1, the word "of" should appear before "a" (second occurrence).

2) Applicant's election with traverse of Group I, claims 8-15, in the reply filed on November 19, 2004 is acknowledged. The traversal is on the ground(s) that an examination of all currently pending claims would not pose an undue burden on the examiner. This is not found persuasive because the searches for the different inventions are not coextensive as set forth in the restriction requirement of September 15, 2004. Searches for the different inventions would require divergent fields of patent search in classes 549, 546, 548 and 436 as well as different searches in the technical literature. Further, different patentability considerations are involved among the different groups; a reference which would anticipate or render obvious the members of one group would not necessarily render obvious the members of any other group. Claims 8-15 are treated on the merits in this Office action.

The requirement is still deemed proper and is therefore made FINAL.

3) Although specific claims may be discussed cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 recites "a chemiluminescent substrate delivery system". Claim 8 uses different language and makes further reference to "the chemiluminescent substrate" and "the

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substrate delivery system". The language of claim 8 does not make it clear whether or not the depicted structure is the entire "chemiluminescent substrate delivery system" of claim 1.

b) In claim 8, the definition of the variable "X" as being "an enzyme-labile group", apparently a group which is capable of being enzymatically activated, appears to be inconsistent with the term "enzymatically activated" of claim 1 which implies that the group "X" is already in an "enzymatically activated" state.

6) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7) Claims 8, 10, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **a)** Tomalia et al (US 5,338,532) taken in combination with the admitted prior art as set forth at page 6 of the instant specification.

Tomalia et al describe conjugates of dendrimers with a wide variety of detectable moieties including optically detectable moieties. The Tomalia et al description includes polyamidoamide (PAMAM) dendrimers, the same dendrimers as the elected species of the instant application (see the response of November 19, 2004, page 3), and the use of linking groups (or "connectors") to link the polymer and detectable moieties, the use of which linkers avoids steric hindrance between the detectable moiety and the dendrimer. See Tomalia et al: col. 6, line 61 – col. 7, line 20; col. 8, lines 32 – 35; col. 4, line 48 – col. 5, line 35; col. 12, line 54 – col. 13, line 28; col. 15, lines 15 – 50.

The description of page 6 of the instant specification (admitted prior art) establishes that dioxetane enzyme substrates of the type used in the conjugates of instant claims 8-15 are well known optically detectable, chemiluminescent moieties.

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Given the fact that dendrimers conjugated to a wide variety of optically detectable groups through linker moieties are well known in the art (Tomalia et al), it would be obvious to substitute other, equivalent, well known optically active moieties such as the dioxetane enzyme substrates of the admitted prior art in the conjugates of Tomalia et al, as claimed, with the expectation of obtaining a similarly useful dendrimer conjugate.

8) Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **a)** Tomalia et al (US 5,338,532) taken in combination with the admitted prior art as set forth at page 6 of the instant specification and with **b)** Simons (Bioconjugate Chemistry (1999), vol. 10, pp. 3-8).

References **a)** are applied for the reasons stated in paragraph **7)** above.

Simons is applied for its description of well known spacers (linkers) useful in the preparation of bioconjugates. Simons specifically describes the use of a diamine spacer which corresponds to the linker $-\text{NH}-(\text{CH}_2)_n-\text{NH}-$ {i.e. $-\text{B}-(\text{CH}_2)_n-\text{B}-$ wherein B is NH of instant claims 9, 11, 13 and 15}.

Given the fact that dendrimers conjugated to a wide variety of optically detectable groups through linker moieties are well known in the art (Tomalia et al), it would be obvious to substitute other, equivalent, well known optically active moieties such as the dioxetane enzyme substrates of the admitted prior art in the conjugates of Tomalia et al, as claimed, with the expectation of obtaining a similarly useful dendrimer conjugate. The substitution of one well known linker for another in the conjugate of Tomalia et al, for example, the linker of Simons, constitutes an obvious variation in a parameter which is routinely modified in the art and which has not been described as critical to the practice of the invention.

9) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 01, 2005



Mary (Molly) E. Ceperley
Primary Examiner
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